UNITED STATES DISTRICT COURT DISTRICT OF NEW HAMPSHIRE

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Marine Polymer Technologies, Inc.,	*	
Plaintiff,	*	
,	*	
v.	*	Civil Action No. 06-CV-100-JD
	*	
HemCon, Inc.,	*	
Defendant	*	
	*	

HEMCON, INC.'S BRIEF RE: PATENT CLAIM CONSTRUCTION

The Defendant, HemCon, Inc. ("HemCon"), submits the within Brief re: Patent Claim Construction pursuant to the Court's Procedural Order dated July 26, 2007, Docket Entry No. 41.

I. INTRODUCTION

U.S. Patent No. 6,864,245 (the '245 patent) is titled "Biocompatible Poly- β -1 \rightarrow 4-N-Acetylglucosamine." (See U.S. Patent No. 6,864,245, attached as Exhibit 1). It includes twenty-two claims. (See id.) Plaintiff Marine Polymer Technologies, Inc. ("Marine Polymer") alleges that the manufacture and sale of the HemCon family of wound dressings and bandages infringes claims 6, 7, 10 to 14, 17, and 20 to 22 of the '245 Patent.\(^1\) These claims will hereinafter be referred to as "the asserted claims." Plaintiff Marine Polymer has withdrawn its allegations that claims 1 to 5, 8, 9, 15, 16, 18, and 19 of the '245 Patent are infringed. These claims will hereinafter be referred to as "the non-asserted claims." The disputed claim terms are "biocompatible poly- β -1 \rightarrow 4-N-acetylglucosamine" (common to asserted claims 6, 7, and 10 to 14) and "biocompatible poly- β -1 \rightarrow 4-glucosamine" (common to asserted claims 17 and 20 to 22). (See Procedural Order dated 7/26/07, Docket Entry No. 41).

¹ Plaintiff Marine Polymer asserts that claims 6, 7, 10 to 14, 17, and 20 to 22 are infringed. Claims 6 and 17 are independent claims. The remaining claims 7 and 10 to 14 are dependent on claim 6. The remaining claims 20 to 22 are dependent upon claim 17.

The construction of the meaning and scope of the patent claims asserted to be infringed is exclusively within the province of the court. Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995), aff'd, 517 U.S. 370 (1996). Markman claim construction of the asserted claims will confirm that the disputed terms exclude the species of either chitin material or chitosan material² that is derived from animal crustacean outer shells. Good examples of animal "crustacean" are crabs, lobsters, or shrimps, which have hard outer shells and are for this reason called "shell fish." There is no dispute that the accused product -- the HemCon family of wound dressings and bandages -- is made only from the species of chitosan material derived from processing the chitin of the outer shells of crustaceans (shell fish), and specifically pandalus borealis Arctic shrimp. (See Deposition of Simon McCarthy Ph.D., attached as Exhibit 3, page 77); see also Robin J. Moody, HemCon Bandage Stakes Claim to Soldier's Kit Bag, Portland Business Journal, November 7, 2005, attached as Exhibit 4). If the Court construes the disputed terms of the '245 patent as excluding crustacean-sourced material, then the only conclusion that can follow is that HemCon's accused product does not infringe the '245 patent.

Further, Markman claim construction will confirm the following:

(1) the disputed term "biocompatible poly-β-1→4-N-acetylglucosamine" (common to asserted claims 6, 7, and 10 to 14), as a matter of law, must mean the species of material harvested from plant microalgae (microalgae, e.g., diatoms, are living aquatic organisms that capture light energy through photosynthesis, using it to convert inorganic substances into organic matter), and more particularly a species of microalgae that is free of protein, substantially free of other organic contaminants, substantially free of inorganic contaminants, has about 4,000 to

² Chitosan is derived by chemical processing of a naturally occurring sugar compound called chitin, which is found in abundance in a wide variety of living plant and animal organisms. (See U.S. Patent Number 5,219,749, column 1, attached as Exhibit 2 (note: this is cited reference in

about 150,000 N-acetylglucosamine monosaccharides covalently attached in a β -1 \rightarrow 4 conformation, and a minimum molecular weight of about 800,000 daltons; and

(2) "biocompatible poly- β -1 \rightarrow 4-glucosamine" (common to asserted claims 17 and 20 to 22), as a matter of law, must mean the species of material harvested from plant microalgae, and more particularly the species of microalgae that is free of protein, substantially free of other organic contaminants, substantially free of inorganic contaminants, has about 4,000 to about 150,000 N-acetylglucosamine monosaccharides covalently attached in a β -1 \rightarrow 4 conformation, and a minimum molecular weight of about 640,000 daltons.

There are seven independent, substantive, and consistent reasons for this Court to construe or define the disputed terms of the '245 patent as proposed by HemCon:

- 1. The explicit definition of the terms provided in the specification of the '245 patent is as follows: "The material [poly-β-1→4-N-acetylglucosamine and poly-β-1→4-N-glucosamine] produced in the present invention is highly crystalline and is produced from carefully controlled, aseptic cultures of one of a number of marine microalgae, preferably diatoms, which have been grown in a defined medium." (U.S. Patent No. 6,864,245, attached as Exhibit 1, col. 4, lines 21-26). This reason is more specifically addressed in II(A) below.
- 2. The specification of the '245 patent expressly denigrates of the use of crustacean shells: "For example, the properties of 'chitins' isolated from conventional sources such as crustacean outer shells and fungal mycelial mats are unpredictably variable. Such variations are due not only to species differences but are also due to varying environmental and seasonal effects that determine some of the biochemical characteristics of the 'chitin'-producing species. In fact, the unpredictable variability of raw material is largely responsible for the slow growth of chitin-based industries." Id. at col. 3, lines 39-47. This reason is more specifically addressed in II(B).

- 3. In combination with Marine Polymer's express denigration of the use of crustacean shells, there is a total absence of any alternative material example other than microalgae disclosed in the specification of the '245 patent. In this regard, Marine Polymer cannot point to a single example in the '245 patent where crustacean shells are used or even why such material would be substituted. This reason is more specifically addressed in II(C).
- 4. In obtaining the earlier issuance of its related U.S. Patent 6,743,783 (the '783 patent), which has a specification identical to that of the '245 patent, Marine Polymer asserted that chitin and chitosan from crustacean shells are not a substitute for the microalgal chitin and chitosan disclosed in the specification of the '245 patent. This reason is more specifically addressed in II(D)(1).
- 5. In obtaining the earlier issuance of its related U.S. Patent 6,686,342 (the '342 Patent), Marine Polymer accepted Patent Examiner Fonda's reasons for allowance of claim terms, which are identical to the claim terms at issue here, that expressly excluded crustacean-based chitin and chitosan materials disclosed in the prior art -- because the material claimed by the applicant is different as to "number of monosaccharides or molecular weight," i.e., the claimed material excludes crustacean-based chitin and chitosan of the prior art and, instead, covers microalgae. This reason is more specifically addressed in II(D)(2).
- 6. In obtaining the issuance of the '245 Patent, Marine Polymer failed to inform a different patent examiner (Patent Examiner Krishnan) that it wanted to rescind the above-identified positions taken and accepted in order to secure the allowance of the claims of the earlier issued related '783 and '342 patents. As a matter of law, the scope of the claims of the '245 patent cannot be construed to be greater than the scope of the claims of either the '783 patent or the '342 patent, both of which exclude crustacean-based chitin and chitosan materials from their scope. This reason is more specifically addressed in II(D)(3).

7. At the outset of prosecution of the '245 patent, the inventors filed statements with the United States Patent and Trademark Office ("USPTO"), which were under oath and under pains and penalties of perjury, that their claimed inventions are limited to "biocompatible poly- β - $1\rightarrow$ 4-N-acetylglucosamine" that is free of protein, substantially free of other organic contaminants, substantially free of inorganic contaminants, has about 4,000 to about 150,000 N-acetylglucosamine monosaccharides covalently attached in a β - $1\rightarrow$ 4 conformation, and a minimum molecular weight of about 800,000 daltons; and "biocompatible poly- β - $1\rightarrow$ 4-glucosamine" that is free of protein, substantially free of other organic contaminants, substantially free of inorganic contaminants, has about 4,000 to about 150,000 N-acetylglucosamine monosaccharides covalently attached in a β - $1\rightarrow$ 4 conformation, and a minimum molecular weight of about 640,000 daltons molecular weight ranges of no less than 800,000 Daltons for poly- β - $1\rightarrow$ 4-N-acetylglucosamine and 640,000 Daltons for poly- β - $1\rightarrow$ 4-N-glucosamine. This reason is more specifically addressed in II(E).

For any one of these reasons, the only reasonable construction of the disputed claim terms is (i) one which excludes chitin and chitosan that is derived from animal crustacean outer shells and (ii) one that is limited to the species of material harvested from plant microalgae, and more particularly the species of microalgae that is free of protein, substantially free of other organic contaminants, substantially free of inorganic contaminants, has about 4,000 to about 150,000 N-acetylglucosamine monosaccharides covalently attached in a β -1 \rightarrow 4 conformation, and a minimum molecular weight ranges of no less than 800,000 Daltons for poly- β -1 \rightarrow 4-N-glucosamine.

This case is ripe for <u>Markman</u> claim construction, because it can be conducted based solely on the already available intrinsic evidence relating to the patent-in-suit; i.e. claims, the specification, and the prosecution history. <u>See Vitronics Corp. v. Conceptronic, Inc.</u>, 90 F.3d 1576, 1582 (Fed. Cir. 1996) ("intrinsic evidence" is the patent itself; including the claims, the

specification, and the prosecution history). Further, no reference to expert testimony is necessary. The specification and prosecution histories of the '245 patent and its related patents are not ambiguous. They unmistakably exclude crustacean-sourced materials from an appropriate claim construction.

In most situations, an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term. In such circumstances, it is improper to rely on extrinsic evidence.... In those cases where the public record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper. The claims, specification, and file history, rather than extrinsic evidence, constitute the public record of the patentee's claim, a record on which the public is entitled to rely. In other words, competitors are entitled to review the public record, apply the established rules of claim construction, ascertain the scope of the patentee's claimed invention and, thus, design around the claimed invention. See Markman, 52 F.3d at 978-79, 34 USPQ2d at 1329. Allowing the public record to be altered or changed by extrinsic evidence introduced at trial, such as expert testimony, would make this right meaningless.

<u>Id.</u> at 1583 (emphasis added) (quotation and citations omitted).

II. THIS IS NOT A CLOSE CASE; THERE IS NO INFRINGEMENT.

A. The '245 Patent Specifies Only Microalgae-Sourced Material

Marine Polymer's now-terminated motion for summary judgment proposed definitions for both "biocompatible poly- β -1 \rightarrow 4-Nacetylglucosamine" and "biocompatible poly- β -1 \rightarrow 4-N-glucosamine." These proposed definitions are, first, an admission that the "ordinary meaning" of the terms does not apply to their construction as a matter of law. Second, Marine Polymer's previously proposed definitions require this Court to use the defining terms "biomedically pure," "reproducibly exhibits," "acceptably low," and "adverse bioreactivity."

Only the term "biomedically pure" has antecedent basis in the specification of the '245 patent. (See U.S. Patent No. 6,864,245, attached as Exhibit 1, at col. 4, lines 16-26). None of the other terms appears anywhere in the specification of the '245 patent. (See id.). Importantly, when the term "biomedically pure" does appear in the specification, it does so in the following context:

The importance of the present invention resides in the fact that the problem of unpredictable raw material variability has been overcome. It is, for the first time, possible to produce, by simple means, and on a commercial scale, biomedically pure, p-GlcNAc of high molecular weight and consistent properties. The material produced in the present invention is highly crystalline and is produced from carefully controlled, aseptic cultures of one of a number of marine microalgae, preferably diatoms, which have been grown in a defined medium.

(See id. (emphasis added)).

This context is important, because it illustrates that the only time the term "biomedically pure" is used in the specification of the '245 patent is in conjunction with an explicit definition of the invention presented in the specification: "The material produced in the present invention is highly crystalline and is produced from carefully controlled, aseptic cultures of one of a number of marine microalgae, preferably diatoms, which have been grown in a defined medium." (See id.). This definition is completely consistent with HemCon's construction of the disputed terms. (See supra at I).

It is well settled that a patentee can "choose to be his or her own lexicographer by clearly setting forth an explicit definition for a claim term that could differ in scope from that which would be afforded by its ordinary meaning." Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1342 (Fed. Cir. 2001). "The specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). Where, as here, the patentee has clearly defined a claim term, that definition "usually . . . is dispositive; it is the single best guide to the meaning of a disputed term." See id.

Further, where, as in the '245 patent, only one embodiment of the invention has been disclosed, the Court of Appeals for the Federal Circuit has repeatedly affirmed the rulings of district courts, that the specification defines the invention:

The district court correctly ruled that the **specification defines the invention** as the use of a single DNA construct to introduce the linked human interferon gene

and selectable marker gene into the host Chinese hamster ovary cell, and that the method and cell claims, as well as the construct claims, are so limited. See *Netword, LLC v. Centraal Corp.*, 242 F.3d 1347, 1352, 58 USPQ2d 1076, 1079 (Fed. Cir. 2001) ("Although the specification need not present every embodiment or permutation of the invention and the claims are not limited to the preferred embodiment of the invention, **neither do the claims enlarge what is patented beyond what the inventor has described as the invention."**) (citations omitted); *cf. SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1341, 58 USPQ2d 1059, 1062-63 (Fed. Cir. 2001) ("Where the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent, even though the language of the claims, read without reference to the specification, might be considered broad enough to encompass the feature in question.")

Biogen, Inc. v. Berlex Labs., 318 F.3d 1132, 1140 (Fed. Cir. 2003) (emphasis added).

The '245 patent offers clear, correct, contextual guidance for determining the appropriate meaning of the terms "biocompatible poly- β -1 \rightarrow 4-N-acetylglucosamine" and "biocompatible poly- β -1 \rightarrow 4-N-glucosamine." "The material [biocompatible poly- β -1 \rightarrow 4-N-acetylglucosamine or biocompatible poly- β -1 \rightarrow 4-N-glucosamine] produced in the present invention is highly crystalline and is produced from carefully controlled, aseptic cultures of one of a number of marine microalgae, preferably diatoms, which have been grown in a defined medium." (See U.S. Patent No. 6,864,245, attached as Exhibit 1, col. 4, lines 21-26). Any other definition directly contravenes the express instruction, definition, implication, and context of the specification of the '245 patent.

This position is consistent with the case law:

One of the best ways to teach a person of ordinary skill in the art how to make and use the invention is to provide an example of how to practice the invention in a particular case. Much of the time, upon reading the specification in that context, it will become clear whether the patentee is setting out specific examples of the invention to accomplish those goals, or whether the patentee instead intends for the claims and the embodiments in the specification to be strictly coextensive. The manner in which the patentee uses a term within the specification and claims usually will make the distinction apparent.

Phillips v AWH Corp., 415 F.3d 1303, 1323 (Fed. Cir. 2005) (en banc), cert. denied, 546 U.S. 1170 (2006) (citations and quotation omitted).

Because the specification "is the single best guide to the meaning of a disputed term … the construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." Phillips v. AWH

Corp., 415 F.3d at 1315 -16; accord nCube Corp. v. SeaChange Int'l, Inc., 436 F.3d 1317 (Fed. Cir. 2006). The role of the specification is to present a description of the technologic subject matter of the invention, while the role of the claims is to point out with particularity the subject matter that is patented. The claims are directed to the invention that is described in the specification; they do not have meaning removed from the context from which they arose. See Netword, LLC v. Centraal Corp., 242 F.2d 1347, 1352 (Fed. Cir. 2001).

It is abundantly clear from the context of the specification of the '245 patent that the patentee never contemplated crustacean shells as a usable alternative to microalgae. In fact, no alternative to microalgae is ever presented. Microalgae are identified as the genus of the invention, with diatoms being the preferred species. (See'245 patent, attached as Exhibit 1, col. 4, line 25).

B. The '245 Patent Denigrates the Use of Crustacean Shell Material.

The specification of the '245 patent explicitly denigrates material derived from animal crustacean outer shells, and instead teaches the use of a purified ("biocompatible") form of material derived from aseptic cultures of microalgae. In the Background of the Invention, the specification of the '245 patent explicitly denigrates "chitins" or "chitosans" isolated from crustacean outer shells, because they are "unpredictably variable." (See id. at col. 3, line 41). The specification of the '245 patent states:

Such variations are due not only to species differences but are also due to varying environmental and seasonal effects that determine some of the biochemical characteristics of the "chitin"-producing species. In fact, the unpredictable variability of raw material is largely responsible for the slow growth of chitin based industries The unpredictable variability of these preparations, as described above, however, severely limits the utility of these heterogeneous compounds. For example, the currently available "chitins" and "chitosans" give

rise to irreproducible data and to unacceptably wide variations in experimental results. Additionally, the available preparations are not sufficiently homogenous or pure, and the preparation constituents are not sufficiently reproducible for these preparations to be acceptable for use in applications, especially in medical ones. Thus, although extremely desirable, true, purified preparations of chitin and chitosan, whose properties are highly reproducible and which are easily manufactured, do not currently exist.

(Id. at col. 3, lines 41-46 and col. 3, line 60 to col. 4, line 6).

Where a specification explicitly excludes a particular feature, that feature is deemed to be outside the reach of the claims of the patent, even though the language of the claims, read without reference to the specification, might be considered broad enough to encompass the feature in question. See Honeywell International, Inc. v. ITT Industries, Inc., 452 F.3d 1312, 1318-1319 (Fed. Cir. 2006). If the written description could talk, it would say "Do not use crustacean outer shells." Cf. Honeywell International, Inc. v. ITT Industries, Inc., 452 F.3d at 1319 ("If the written description could talk, it would say, 'Do not use carbon fibers."). As concluded in Honeywell International, Inc. v. ITT Industries, Inc.: "... the written description has gone beyond expressing the patentee's preference for one material over another. Its repeated derogatory statements concerning one type of material are the equivalent of disavowal of that subject matter from the scope of patent's claims." Id. at 1320.

There is also an aspect of basic fairness to this result. The public is entitled to take the patentee at his or her word, and the word of the '245 patent is "don't use crustacean outer shells – use my microalgae-based invention instead." A patent specification serves a public notice function. Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 922 (Fed. Cir. 2004). In the patent specification, an "inventor's discussion of the disadvantages of [] prior art sheds light on the scope of the invention." Kinik Co. v. ITC, 362 F.3d 1359, 1365 (Fed. Cir. 2004). Indeed, "the inventor's intention, as expressed in the specification, is regarded as dispositive." Phillips v. AWH Corp., 415 F.3d at 1316 (citation omitted). "[S]ince, by distinguishing the claimed invention over the prior art, an applicant is indicating what the claims do not cover, he is by

implication surrendering such protection." <u>Ekchian v. Home Depot, Inc.</u>, 104 F.3d 1299, 1304 (Fed. Cir. 1997) (citation omitted). All representations made by or on behalf of an inventor, and upon which the public may rely, limits the interpretation of the claims so as to exclude disclaimed subject matter. <u>See id.</u>

C. The '245 Patent Requires the Use of Microalgae and Fails to Demonstrate How Crustacean Shell Material Could Ever Be Substituted For Microalgae.

In the specification of the '245 patent, every example of the invention that is given requires the use of material derived or harvested from microalgae, specifically diatoms. (See U.S. Patent No. 6,864,245, attached as Exhibit 1, cols. 8-71). In section 6.1 of the "Description of the Preferred Embodiment" the '245 patent states: "The p-GlcNAc membranes used in the IR studies were prepared by either the Mechanical Force purification method as described, above, in Section 5.3.1, or by the Chemical/Biological purification method, as described, above, in Section 5.3.2, as indicated." Id. at col. 38, lines 52-56. Reference to Section 5.3.1 (Mechanical Force purification) and Section 5.3.2 (Chemical/Biological purification) state, respectively: 1. "The p-GlcNAc fibers may be separated from diatom cell bodies by subjecting the contents of the culture to an appropriate mechanical force." (id. at col. 14, lines 3-5 (emphasis added)), and 2. "In this method, p-GlcNAc fibers are separated from diatom cell bodies by subjecting them to chemical and/or biological agents as described in more detail below." (id. at col. 14, lines 36-38 (emphasis added)). Additionally, section "5.2.1. Microalgal Sources of p-GlcNAc" of the specification states: "The p-GlcNAc of the invention is produced by, and may be purified from, microalgae, preferably diatoms." (<u>Id</u>. at col. 10, lines 66-67 (emphasis added)).

Conversely, crustacean shells, such as shrimp shells, are not disclosed or identified in any examples given in the specification as to how to practice the invention and are discussed only in the negative: "For example, the properties of "chitins" isolated from conventional sources such as crustacean outer shells and fungal mycelial mats are unpredictably variable In fact, the

unpredictable variability of raw material is largely responsible for the slow growth of chitin-based industries." (Id. at col. 3, lines 39-47).

Marine Polymer has previously contended that, because it criticized both prior art microalgal and crustacean materials, its claims must be construed to include both microalgal and crustacean sources. This is contrary to the law. Marine Polymer's error is especially egregious in view of the undisputed fact that the only examples of material provided in the specification to demonstrate how to practice the invention are microalgal. Marine Polymer erroneously urges the Court to ignore the specification and the context in which the information contained therein is presented. ZMI Corp. v. Cardiac Resuscitator Corp. reversed a finding of infringement, reasoning as follows:

Patent law allows an inventor to be his own lexicographer. The specification aids in ascertaining the scope and meaning of the language employed in the claims inasmuch as words must be used in the same way in both the claims and the specification.... The district court largely **ignored the specification** in interpreting the claims, making only passing reference in its opinion to the specification and then only to point to a change made prior to filing the patent application.

844 F.2d 1576, 1580 (Fed. Cir. 1988) (emphasis added, citations and internal quotes omitted).

D. Marine Polymer is Bound by the Arguments it Made to the United States Patent And Trademark Office, and the Statements of the Patent Examiners That it Ratified in Connection with its Prosecution of Related Patents.

Marine Polymer Patent US 6,743,783 (the '783 Patent) (see U.S. Patent No. 6,743,783, attached as Exhibit 5) and Marine Polymer Patent US 6,686,342 (the '342 Patent) (see U.S. Patent No. 6,686,342, attached as Exhibit 6) are part of the family of fifteen Marine Polymer patents that include the '245 Patent. Like other patents in the Marine Polymer family, the '783 Patent, the '342 Patent, and the '245 Patent share a substantially similar specification. The laterissued '245 Patent is also legally related to the earlier issued '783 Patent and the earlier issued '342 Patent by a terminal disclaimer, which Marine Polymer was required to file in order to gain

allowance of the claims of the '245 Patent. (See Excerpts from the Prosecution History of the '245 Patent, attached as Exhibit 7, pp. 87, 95).

Where both the earlier-issued '783 patent and the '342 patent are related to the later issued '245 patent, the very arguments that Marine Polymer made to secure issuance of the '783 patent and the '342 patent now require crustacean material to be excluded from any legal construction of the disputed terms of the '245 patent. Where "[t]he patentee made a clear and unmistakable disclaimer of claim scope in its prosecution of the parent ... patent, ... we presume, unless otherwise compelled, that the same claim term in the same patent or related patents carries the same construed meaning." Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1334 (Fed. Cir. 2003), citing Fin Control Sys. Pty, Ltd. V. OAM, Inc., 265 F.3d 1311, 1318 (Fed. Cir. 2001). Where a disclaimer affecting the meaning of a claim has been made in respect to the prosecution of one related patent (for example by argument to distinguish prior art or acceptance of a reason given by the United States Patent and Trademark Office ("USPTO") in allowing a patent to issue), that disclaimer affects all other related patents containing that same term. See id. at 1334 ("Consequently, because the prosecution disclaimer made in the '880 patent extends to the '679 patent, we conclude that any energy directed inside the energy zone cannot add appreciable heat to the energy zone as to affect the accuracy of the temperature measurement.").

1. Marine Polymer Is Bound By Its Statements To Secure The Allowance of The '783 Patent of the '245 Patent Family.

Claim 1 of the earlier-issued '783 Patent is directed to the use of a poly- β -1 \rightarrow 4-N-acetylglucosamine derived from a <u>microalgal</u> source (i.e., plant diatoms) for hemostatis, and reads: "A pharmaceutical composition suitable for hemostasis comprising an amount of a <u>microalgal</u> poly- β -1 \rightarrow 4-N-acetylglucosamine, or derivative thereof, effective for hemostasis, wherein the <u>microalgal</u> poly- β -1 \rightarrow 4-N-acetylglucosamine or derivative thereof is formulated

into a shape or configuration <u>suitable for hemostasis</u>." (See U.S. Patent Number 6,743,783, attached as Exhibit 5, Column 7, lines 10-16). Marine Polymer has not asserted the '783 Patent (or any other patent except the '245 Patent) against HemCon.

During the course of prosecution of the '783 Patent, Patent Examiner Fonda, in her prior art search, found prior art patents (U.S. Patent 4,575,519 to Kifune, attached as Exhibit 8) (U.S. Patent 3,988,411 to Capozza, attached as Exhibit 9), which show the use of crustacean source chitin as hemostatis material. Examiner Fonda contended that it would be obvious, in view of these prior art patents, to substitute a microalgae-source chitin for a crustacean source chitin.

(See Excerpts from the Prosecution History of US 6,743,783, attached as Exhibit 10, pp. 3 to 6). Marine Polymer disagreed, arguing:

... the Examiner's obviousness rejection rests on the notion that one skilled in the art would be motivated to substitute the insect and crustacean chitin as a starting material in the formulations of [the prior art cited by the Examiner] with microalgal poly-- β -1 \rightarrow 4-N-acetylglucosamine ... [The prior art cited by the Examiner] both fail to even provide the motivation necessary to look beyond their teachings and combine these teaches with those of Falk or McLachlan [which disclose the use of microalgae chitin].

(See id. at. 12).

In this argument, affirmatively made during the prosecution of the '783 Patent to obtain allowance of patent claims, Marine Polymer expressly disclaimed the interchangeability of chitin material made from microalgal sources as disclosed in the '783 Patent (which is the same invention disclosed in the '245 Patent) and chitin material made from crustacean sources. This position is, of course, consistent with the written description of the '783 Patent, which the '245 Patent shares. However, Marine Polymer cannot now attempt, in the interpretation of the claims of the subsequent related sibling (the '245 Patent), to recapture a claim scope that has been previously disclaimed.

Marine Polymer cannot have it both ways: to argue in one setting that chitin from crustacean sources is different than the disclosed invention and to argue in a later setting that

chitin from crustacean sources is the same as the disclosed invention. Where a patentee unequivocally imparts a novel meaning to claim terms or expressly relinquishes claim scope during patent prosecution, "[t]he doctrine of prosecution disclaimer [which] is well established in Supreme Court precedent, preclude[es] patentees from recapturing through claim interpretation specific meanings disclaimed during prosecution." Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1323 (Fed. Cir. 2003). Not only does prosecution disclaimer prevent recapture in the corresponding application, but "[a]n interpretation asserted in the prosecution of a parent application can also affect continuation applications, continuation-in-part applications, and even related continuation-in-part applications arising from the same parent." Id. at 1333 (citing Elkay Mfg. Co. v. Ebco Mfg. Co., 192 F.3d 973, 980 (Fed. Cir. 1999); Wang Labs., Inc. v. Am. Online, Inc., 197 F.3d 1377, 1384 (Fed. Cir. 1999); and Jonsson v. Stanley Works, 903 F.2d 812, 818 (Fed. Cir. 1990)). "Claim language 'must be read consistently with the totality of the patent's applicable prosecution history,' including parent applications." Anderson Corp. v. Fiber Composites, LLC, 474 F.3d 1361, 1368 (Fed. Cir. 2007) (quoting Biovail Corp. v. Andrx Pharms., Inc., 239 F.3d 1297, 1301 (Fed. Cir. 2001)).

2. Marine Polymer is Bound by its Ratification of the Examiner's Statements Made in Allowing the '342 Patent

Just as importantly, Marine Polymer fails to bring to the Court's attention its ratification of Patent Examiner Fonda's reasons for allowing the claims of another earlier issued related U.S. Patent 6,686,342 (the '342 patent, attached as Exhibit 6) based upon Examiner Fonda's distinction of prior U.S. Patents to Kifune (Exhibit 8) and Capozza (Exhibit 9). The disputed term "biocompatible poly- β -1 \rightarrow 4-N-acetylglucosamine" in the '245 patent is used identically in claim 23 of the '342 patent. Similarly, the disputed term "biocompatible poly- β -1 \rightarrow 4-N-glucosamine" in the '245 patent is used identically in claim 37 of the '342 patent.

In allowing the '342 patent to issue, the Patent Examiner Fonda specifically stated:

No prior art of record teaches or fairly suggests the N-acetylglucosamines as claimed. The Examiner notes that each of FALK (BA) and McLACHLAN & CRAIGIE (BM) teaches an N-acetylglucosamine material made from the same microalgal source as taught by Applicant [Marine Polymer], and purported to be pure. Therefore, FALK and McLACHLAN & CRAIGIE are considered to be the closest prior art. However, the Cole declaration, made of record in this case on 08-11-03, provides evidence to show that the material of FALK or McLACHLAN & CRAIGIE is not biocompatible or immunoneutral, because it is not suitably pure or reproducibly produced. Thus, neither FALK nor McLACHLAN & CRAIGIE teaches or fairly suggests the N acetylglucosamines as claimed.

The Examiner also notes that each of KIFUNE (CM) and CAPOZZA (AC) teaches that poly- β -1-4-N-acetylglucosamine, which is sometimes used interchangeably with the term "chitin," may be formulated as a shaped article for use in the biomedical field. See KIFUNE, column 3, lines 20-22 and column 3, lines 47-48; and CAPOZZA, columns 5-6 and column 8, lines 48-49. However, neither KIFUNE nor CAPOZZA teaches or suggests the claimed ranges for number of monosaccharides or molecular weight. Furthermore, the Cole Declaration, made of record in this case on 08-11-03, provides evidence of unexpected results as to purity and reproducibility of production for the materials of the instant invention.

(Notice of Allowability, App. No. 10/386,893, attached as Exhibit 11, at MP054806-07 (emphasis added)).

Therefore, the intrinsic evidence expressly discloses that Patent Examiner Fonda acknowledged that material disclosed in the identical specification is microalgae ("an N acetylglucosamine material made from the same microalgal source as taught by Applicant [Marine Polymer]"). The terms "biocompatible poly-β-1→4-N-acetylglucosamine" and "biocompatible poly-β-1→4-N-glucosamine" can only be construed to mean microalgae-sourced material. This is so because the claims of the related '342 patent require a specific number of monosaccharides or molecular weight. These specific requirements exclude the crustacean based materials disclosed by Kifune and Capozza, and convinced Patent Examiner Fonda to allow the claims of the related '342 patent over the prior art. Consequently, the disputed claim terms of the '245 patent must be construed to cover microalgae-sourced material recognized by Patent Examiner Fonda as the "microalgal source taught by Applicant." Those same terms must be

construed to exclude prior art crustacean sourced material, recognized by Patent Examiner Fonda as "poly-β-1-4-N-acetylglucosamine, which is sometimes used interchangeably with the term 'chitin,' [and] may be formulated as a shaped article for use in the biomedical field ... [because the prior art does not teach or suggest] the claimed ranges for number of monosaccharides or molecular weight"). In this way, the scope of the claims of the '245 patent is not improperly expanded beyond the scope of either the '342 patent or the '783 patent.

Marine Polymer is estopped from asserting a claim interpretation that is inconsistent with the distinction of the prior art made by Patent Examiner Fonda with respect to terms in the related '342 patent, which are identical to the disputed terms in the '245 patent. Marine Polymer's proposed construction necessarily requests the Court to alter the prosecution histories of the '783 patent and the '342 patent so that the definition of the disputed terms of the '245 patent recaptures the crustacean-based materials of both Kifune and Capozza that were expressly excluded by the USPTO. Marine Polymer cannot recapture the claim scope that was surrendered or disclaimed. See Omega Engineering, Inc. v Raytek Corp., 334 F.3d 1314, 1323 (Fed. Cir. 2003) ("The doctrine of prosecution disclaimer is well established in Supreme Court precedent, precluding patentees from recapturing through claim interpretation specific meanings disclaimed during prosecution.").

Further, in September 2005, prior to the filing of this lawsuit, and, again, in June 2006, after this lawsuit was filed, the USPTO (a new Patent Examiner Krishnan) rejected claims filed by Marine Polymer in a related continuation application that included no molecular weight or monosaccharide limitations. The USPTO did so citing crustacean-based chitin and chitosan prior art patents. (See Excerpts from the Prosecution of Application Serial No. 10/859,682, attached as Exhibit 12, at pp. 19-20, 40-41). In rejecting these claims as anticipated under 35 U.S.C. § 102(b), the USPTO concluded that Marine Polymer was claiming "old and well known" (i.e., crustacean-sourced) materials. (Id. at 19-20). Marine Polymer tried to argue the point in

response to this rejection, and was again rejected. It then abandoned its application. (<u>Id.</u> at 33-35; 40-44).

3. Marine Polymer's Different Approaches with Two Different Patent Examiners

As established <u>supra</u> at II(1) and II(2), the later-filed application for the '245 patent was reviewed by Patent Examiner Ganapathy Krishnan, while the earlier filed applications for the related '783 patent and '342 patent were considered by a different patent examiner, Kathleen K. Fonda. Marine Polymer can point to no instance, while the applications for all three patents were co-pending, where it apprised Patent Examiner Krishnan of the earlier substantive positions it had taken before Examiner Fonda during the prosecution of the related applications for the '783 patent and the '342 patent.

The '245 Patent was filed about four months after the first HemCon bandage was introduced. The examination of the '245 Patent was conducted by Examiner Krishnan, who had not been involved in the examination of any of the preceding Marine Polymer patents. Marine Polymer filed a first preliminary amendment with claims to a biocompatible N-acetylglucosamine or a biocompatible glucosamine with the expressed higher molecular weight range of previous Marine Polymer patents (i.e., 800,000 daltons to 30 million daltons or about 640,000 daltons to about 2.4 million daltons). (See Exhibit 7, pp. 14 to 17). In the first office action, Examiner Krishnan found these claims to be allowable, except for an obviousness type double patent rejection that could be overcome by Marine Polymer's filing of a terminal disclaimer. (See Excerpts from the Prosecution History of the '245 Patent, attached as Exhibit 7, pp. 21-22).

In an amendment filed on June 14, 2007 responding to Examiner's first office action,

Marine Polymer expanded the claims by amendment to remove the lower molecular weight

value in the range, such that the molecular weight limitation that used to read -- about 800,000

daltons to about 30 million daltons or about 640,000 daltons to about 24 million daltons -- now read -- "up to about 30 million daltons" or "up to about 24 million Daltons." (See Excerpts from the Prosecution History of the '245 Patent, attached as Exhibit 7, pp. 62 to 66).

With a higher molecular weight range defined in the claims of previous Marine Polymer patents, the claims covered the higher molecular weight chitin and chitosan from plant sources, as described in the written description of the '245 Patent: "The p-GlcNac polysaccharide species of the invention is a polymer of high molecular weight average of about 800,000 daltons to about 30 million Daltons" (See U.S. Patent No. 6,864,245, attached as Exhibit 1, column 9, lines 15 to 20). "A poly-β-1→4-glucosamine species of the invention in which each of the monosaccharide units of the poly-β-1→4-N-acetylglucosamine species of the invention has been deacetylated will have a molecular weight of about 640,000 daltons to about 24 million Daltons (See U.S. Patent No. 6,864,245, attached as Exhibit 1, Col. 15, lines 50-56). The "up to" amendment in the '245 Patent for the first time dropped the lower limits of the range from 640,000/800,000 daltons to essentially zero. With the lower molecular weight limits removed, the scope of the claims was expanded to now encompass the molecular weight of <u>any</u> chitin and chitosan from any source, including the animal crustacean sources that had been disclaimed in the earlier '783 Patent and '342 Patent due to the prior art.

Marine Polymer brings forward no evidence that it informed Examiner Krishnan that the practical effect of the amendment was to enlarge the scope of the claims to now encompass the molecular weight of any chitin and chitosan from any source, including the animal crustacean sources that had been disclaimed in the earlier '783 patent and '342 patent. There is no suggestion that Marine Polymer informed Examiner Krishnan that it was attempting to reclaim subject matter previously disclaimed in a previous issued related case (e.g., the '783 patent and the '342 patent), and that prior art considered during the prosecution of the '783 Patent and the '342 patent may now be relevant. As a result, Examiner Krishnan allowed the amended claims

without any consideration of prior art directed to chitin/chitosan derived from crustacean sources of the type found by Examiner Fonda during the prosecution of the '783 Patent. (See Excerpts from the Prosecution History of the '245 Patent, attached as Exhibit 7, p. 82).

With respect to the broadened (now disputed) claim terms of the '245 patent, Marine Polymer advised new Examiner Krishnan that "[n]o new matter is introduced," never informing him that Marine Polymer intended to seek a claim scope for the '245 patent that was broader than the scope of the claims in its related '783 patent and '342 patent (i.e., a claim scope that would include crustacean sourced materials). (See id. at 68).

With regard to this situation, the Court of Appeals for the Federal Circuit has stated:

Hakim [an applicant] had the right to refile the application and attempt to broaden the claims. However, an applicant cannot recapture claim scope that was surrendered or disclaimed. The district court did not err in holding that the examiner's action in allowing the continuation claims without further prosecution was based on the prosecution argument in the parent. Although a disclaimer made during prosecution can be rescinded, permitting recapture of the disclaimed scope, the prosecution history must be sufficiently clear to inform the examiner that the previous disclaimer, and the prior art that it was made to avoid, may need to be re-visited.

Hakim v. Cannon Avent Group, Plc, et al, 2007 U.S. App. LEXIS 3926, *10-11. (Fed. Cir. 2007) (emphasis added, internal citations and quotations omitted); see also Springs Window Fashions LP v. Novo Indus., L.P., 323 F.3d 989, 995 (Fed. Cir. 2003) ("A patentee may not state during prosecution that the claims do not cover a particular device and then change position and later sue a party who makes that same device for infringement.").

There is no evidence that Marine Polymer ever informed Examiner Krishnan, during his review of the application for the '245 patent, of prior positions taken by and before Examiner Fonda in securing the allowance of the related '783 patent and '342 patent. There is no evidence that Marine Polymer ever informed Examiner Krishnan that Marine Polymer wanted to rescind the positions that it had taken and accepted before Examiner Fonda in the '245 patent in order to secure the allowance of the claims of the '783 patent and the '342 patent.

Thus, the scope of the claims of the '245 patent cannot be construed to be greater than the scope of the claims of either the '783 patent or the '342 patent. Such a construction would allow Marine Polymer to wrongly recapture, through claim interpretation, specific meanings disclaimed in the USPTO during prosecution of the applications for the '783 and '342 patents.

The only position that is consistent with specification of the '245 patent, its prosecution history, the prosecution histories of related the related '783 and '342 patents, and the law is that the disputed claim terms must be construed to exclude crustacean-sourced chitin and chitosan materials.

E. The Disputed Claim Terms are Limited to a Definition that is Consistent with the Inventors of the '245 Patent Identification of the Invention under Oath to the United States Patent and Trademark Office.

"The applicant shall make oath that he believes himself to be the original and first inventor of the process, machine, manufacture, or composition of matter, or improvement thereof, **for which he solicits a patent**; and shall state of what country he is a citizen." 35 U.S.C. § 115 (emphasis added). A declaration may be submitted in lieu of an oath. See 35 U.S.C. § 25. Federal regulations require that "A supplemental oath or declaration meeting the requirements of § 1.63 must be filed when a claim is presented for matter originally shown or described but not substantially embraced in the statement of invention or claims originally presented 37 CFR 1.67 (b). 37 CFR 1.63 states, in part, that the oath or declaration must "State that the person making the oath or declaration believes the named inventor or inventors to be the original and first inventor or inventors of the subject matter **which is claimed and for which a patent is sought.**" 37 CFR 1.63 (emphasis added).

Here, when the inventors filed their application for the '245 patent (including a preliminary amendment) they submitted a declaration (from a prior related application filed in 1995 (Serial No. 08/471,290), that stated in relevant part:

As a below named inventor, I hereby declare that: ... I believe I am ... an original, first and joint inventor ... of **the subject matter which is claimed** and for which a patent is sought on the invention entitled METHODS AND COMPOSITIONS FOR POLY-β-1→4-N-ACETYLGLUCOSAMINE CELL THERAPY SYSTEM the specification of which is attached hereto unless one of the following boxes is checked: the specification filed in the United States on June 6, 1995 as Application Serial NO. 08/471,290. ... I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above. I acknowledge the duty to disclose information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, §1.56."

(See Excerpts from the Prosecution History of the '245 Patent, attached as Exhibit 7, pp. 43-44.)³ The signature line reveals the inventors signatures, which are all dated in the year 1995. (See id.). The declaration was made under penalty of perjury as per 18 U.S.C. § 1001. (See id.).

On December 15, 2003 this identical declaration was again filed by the applicants in association with a preliminary amendment of identical date. The "poly- β -1 \rightarrow 4-N-acetylglucosamine" (common to asserted claims 6, 7, and 10 to 14), was identified in Application Serial No. 08/471,290, as claimed, as being limited to material that is free of protein, substantially free of other organic contaminants, substantially free of inorganic contaminants, having about 4,000 to about 150,000 N-acetylglucosamine monosaccharides covalently attached in a β -1 \rightarrow 4 conformation, and a minimum molecular weight of about 800,000 daltons. (See Excerpts of Prosecution History for related United States Patent 5,858,350 (original application serial number 08/471,290), attached as Exhibit 13, at HEM 126418). The "biocompatible poly- β -1 \rightarrow 4-glucosamine" (common to asserted claims 17 and 20 to 22), was identified in Application Serial No. 08/471,290, as claimed, as being limited to material that is free of protein, substantially free of other organic contaminants, substantially free of inorganic contaminants, having about 4,000 to about 150,000 N-acetylglucosamine monosaccharides covalently attached

³ As part of a request for expedited examination dated 26 June 2003, Marine Polymer submitted a new declaration from one of the inventors, Ernst Pariser, but no other inventor made a new declaration of any kind with regard to the invention.

in a β -1 \rightarrow 4 conformation, and a minimum molecular weight of about 640,000 daltons. (<u>Id.</u> at HEM 126419).

Further, in their sworn acknowledgment of their duty to disclose prior art, neither the inventors nor their attorneys ever told Patent Examiner Krishnan that they were seeking a claim scope greater than the scope of the claims to which they had attested under penalty of perjury to be seeking. (See Excerpts from the Prosecution History of the '245 Patent, attached as Exhibit 7, pp. 43-44).

The Court of Appeals for the Federal Circuit has specifically held that where an applicant for a patent seeks to broaden the scope of the claims of his invention by re-filing his application the applicant may do so only if he provides notice to the USPTO Examiner that he or she is seeking a claim scope that is broader than he previously sought. "Although a disclaimer made during prosecution can be rescinded, permitting recapture of the disclaimed scope, the prosecution history must be sufficiently clear to inform the examiner that the previous disclaimer, and the prior art that it was made to avoid, may need to be re-visited." Hakim v.

Cannon Avent Group, Plc, 2007 U.S. App. LEXIS 3926, *10-11. (Fed. Cir. 2007); see also

Springs Window Fashions LP v. Novo Indus., L.P., 323 F.3d 989, 995 (Fed. Cir. 2003) ("The public notice function of a patent and its prosecution history requires that a patentee be held to what he declares during the prosecution of his patent. A patentee may not state during prosecution that the claims do not cover a particular device and then change position and later sue a party who makes that same device for infringement.")."

The record of the '245 patent is devoid of any supplemental oath or declaration that "must be filed when a claim is presented for matter originally shown or described but not substantially embraced in the statement of invention or claims originally presented " 37 CFR 1.67 (b). "The 'presumption of regularity' supports official acts of public officers. In the absence of clear evidence to the contrary, the doctrine presumes that public officers have

properly discharged their official duties." <u>See Jazz Photo Corp. v. U.S.</u>, 439 F.3d 1344, 1351. (Fed. Cir. 2006) (citations omitted).

There is no evidence of record that Marine Polymer ever informed new Patent Examiner Krishnan that Marine Polymer was seeking a claim scope greater than it had previously disclaimed when the inventors attested to their invention and asserted under oath that they were entitled to patent over the prior art that they themselves had cited to the USPTO. No supplemental oath was ever made by the inventors during the prosecution of the '245 patent.

Absent clear and convincing evidence to the contrary, the only reasonable conclusion is that the claims of the '245 patent must be construed as substantially embracing the meaning of the claims originally presented by the inventors in Application Serial No. 08/471,290. The disputed terms of the '245 patent cannot be construed to have a scope greater than the invention which the inventors declared under penalty of perjury in prior Application Serial No. 08/471,290 to be theirs.

Indeed, the proposed constructions for the disputed claim terms "biocompatible poly- β - $1\rightarrow 4$ -N-acetylglucosamine" and "biocompatible poly- β - $1\rightarrow 4$ -glucosamine" are specifically supported by the clear and express statements of the specification of the '245 patent. See, e.g., Exhibit 1: Col. 3, lines 3-6 and Col. 4, lines 13-15 (material that is free of protein, substantially free of other organic contaminants, substantially free of inorganic contaminants); Col. 5, lines 21-23, Col. 9, lines 20-25, and Col. 15, lines 56-61 (material has about 4,000 to about 150,000 N-acetylglucosamine monosaccharides covalently attached in a β - $1\rightarrow 4$ conformation); Col. 9, lines 15-20 ("poly- β - $1\rightarrow 4$ -N-acetylglucosamine" material has a minimum molecular weight of about 800,000 daltons); and Col. 15, lines 50-56 ("poly- β - $1\rightarrow 4$ -glucosamine" material has a minimum molecular weight of about 640,000 daltons)

III. CONCLUSION

With respect to the interpretation of the disputed claim terms of the '245 patent, the only reasonable legal conclusions are that:

- (1) The disputed claim terms in the '245 patent must be construed, consistent with the specification of the '245 patent and the prosecution histories of the '245 patent and the related '783 patent and '342 patent, to exclude animal crustacean-sourced "biocompatible poly- β -1 \rightarrow 4-N-acetylglucosamine" and "biocompatible poly- β -1 \rightarrow 4-N-glucosamine."
- (2) The disputed claim term "biocompatible poly- β -1 \rightarrow 4-N-acetylglucosamine" (common to asserted claims 6, 7, and 10-14) must be construed, consistent with the sworn statements of the inventors of the '245 patent, as being limited to material that is free of protein, substantially free of other organic contaminants, substantially free of inorganic contaminants, has about 4,000 to about 150,000 N-acetylglucosamine monosaccharides covalently attached in a β -1 \rightarrow 4 conformation, and a minimum molecular weight of about 800,000 daltons.
- (3) The disputed claim term "biocompatible poly- β -1 \rightarrow 4-glucosamine" (common to asserted claims 17 and 20 to 22), must be construed, consistent with the sworn statement of the inventors of the '245 patent, as being limited to material that is free of protein, substantially free of other organic contaminants, substantially free of inorganic contaminants, has about 4,000 to about 150,000 N-acetylglucosamine monosaccharides covalently attached in a β -1 \rightarrow 4 conformation, and a minimum molecular weight of about 640,000 daltons.

No other conclusion is remotely consistent with the specification of the '245 patent, its prosecution history or related prosecution histories, or the law.

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CERTIFICATE OF SERVICE

I hereby certify that the within Brief re: Patent Claim Construction has been forwarded to all counsel of record pursuant to the Court's rules and procedures concerning electronic filing. Electronically Served Through ECF: Daniel E. Will, Esq.

Date: August 17, 2007 /s/ Richard B. McNamara